Submitter

Zoe Medical Incorporated
460 Boston Street
Topsfield, MA 01983-1223

APR - 9 2010

Contact Name: James Chickering
Contact Title: Regulatory Affairs Manager
Phone: (978) 887-1410 X37
Fax: (978) 887-1406

Date Prepared: December 4, 2009

Trade Name

Ultraview DM3 Monitor

Common Name

Patient Physiological Monitor (with alarms)

Classification Name

Non-invasive Blood Pressure Measurement System

Classification Regulation

21 CFR 870.1130

Product Code

DXN

Substantially Equivalent Devices

Ultraview DM3 Monitor	Predicate 510(k) Number	Predicate Manufacturer / Model
Non-invasive Blood Pressure component	K090556	Spacelabs Healthcare / élance Vital Signs Monitoring System
Pulse Oximetry component	K090556	Spacelabs Healthcare / élance.Vital Signs Monitoring System
Temperature component	K955846	Cardinal Health / Model 2082 Temp Plus III Thermometer

Device Description

The Ultraview DM3 Monitor is a portable patient monitor intended to be used by clinicians and medical qualified personnel for spot check and continuous monitoring of non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), and temperature.

Technology Comparison

The Ultraview DM3 Monitor utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use

The Ultraview DM3 Monitor is indicated for use by health care professionals for monitoring patient vital signs.

The Ultraview DM3 Monitor is intended for monitoring, recording, and alarming basic vital signs on adult and pediatric patients. Monitored parameters include SpO_2, pulse rate, NIBP, and temperature.

Performance Testing

Category	Testing Summary
Sterilization Validation	The Ultraview DM3 Monitor is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.
Shelf Life Testing	The Ultraview DM3 Monitor is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.
Biocompatibility Testing	The Ultraview DM3 Monitor has no patient contact materials, and therefore this section does not apply to the monitor itself.
Software Testing	Software for the Ultraview DM3 Monitor was designed and developed according to Zoe Medical's software development process, and was verified and validated. Test results indicated that the Ultraview DM3 Monitor complies with its predetermined specification.
Electrical Safety	The Ultraview DM3 Monitor was tested for patient safety in accordance with applicable standards. Test results indicated that the Ultraview DM3 Monitor complies with its predetermined specification.
Electromagnetic Compatibility Testing	The Ultraview DM3 Monitor was tested for EMC in accordance with applicable standards. Test results indicated that the Ultraview DM3 Monitor complies with its predetermined specification.
Performance Testing – Bench	The Ultraview DM3 Monitor was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional, environmental, and shipping and transportation testing.
Performance Testing – Animal	Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Ultraview DM3 Monitor.
Performance Testing - Clinical	Clinical performance testing was performed according to ISO 9919:2005 to demonstrate safety and effectiveness of the oximetry feature of the Ultraview DM3 Monitor.

Conclusion

Based upon a comparison of devices and performance testing results, the Ultraview DM3 Monitor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 9 2010

Zoe Medical
c/o Mr. James Chickering
Regulatory Affairs Manager
460 Boston St.
Topsfield, MA 01983

Re: K093802
Trade/Device Name: Ultraview DM3 Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN, DQA
Dated: March 29, 2010
Received: April 06, 2010

Dear Mr. Chickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

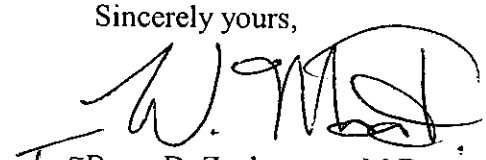
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _K093802_____

Device Name:

Ultraview DM3 Monitor

Indications for Use:

The Ultraview DM3 Monitor is indicated for use by health care professionals for monitoring patient vital signs.

The Ultraview DM3 Monitor is intended for monitoring, recording, and alarming basic vital signs on adult and pediatric patients. Monitored parameters include SpO_2, pulse rate, NIBP, and temperature.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093802